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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,185

12/31/2003

George M. Halow

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7590

09/20/2006

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,185

Applicant(s)

HALOW, GEORGE M.

Examiner

Brian S. Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-21, 23-27, 30, 31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-21, 23-27, 30, 31 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of Application

1. By Amendment filed April 24, 2006, claims 1-3, 5-16, 18, 23-25, 27 and 31 have been amended; claims 4, 22, 28-29 and 32 have been cancelled; and claims 33-37 have been newly added.
2. Claims 1-3, 5-21, 23-27, 30-31 and 33-37 are currently pending for prosecution on the merits.
3. It is noted that this application has been transferred to this Examiner because of the departure of the previous Examiner, Amy Lewis, from USPTO.

Response to Arguments

4. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 15, 27, 30 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims in this application introduce new negative limitations into the instant invention, namely “without cleansing the bowel”. The examiner determines that when all evidences in the original disclosure are considered and carefully reviewed, the newly amended claims fail to find support in the original specification.

The instant invention discloses throughout the specification that in addition to ammonia detoxication in HE, lactulose additionally functions as an osmotic laxative or stool softener by increasing gut solute concentration s and drawing water into he large intestine (page 2, lines 8-23); the osmotic effects of PEG are useful not only for softening the stool and/or increasing bowel motility of constipated HE patients (page 4, lines 7-10); in severe case, one may want to use amounts of PEG suitable for bowel cleansing (page 4, lines 21-22); this composition combines the osmotic properties of lactulose and PEG for laxative/stool softening benefits (page 4, lines 27-33); a proprietary laxative, MiraLax is a useful source of PEG 3350 powder readily soluble in water (page 5, lines 18-20); and PEG or lactulose concentration can be increased or decreased to modulate the desired results of laxative/stool softening benefits, for example moderate or heavy diarrhea if desired initially (page 7, lines 26-35).

As discussed above, it would have been clear to one skilled in the art, reading the instant disclosure, that the instant composition would provide the desired laxative property by increasing bowel motility, emptying the contents in the bowel, or cleansing of the bowel.

As discussed above, the specification only positively states about the boundaries of the claim. There is no express statement about the negative limitation “without cleansing the bowel”

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that can be found in the specification. Thus, the exclusion of said elements implies the inclusion of all other elements not expressly excluded, clearly illustrating that such negative limitations do, in fact, introduce new matter. The negative limitation recited in the present claims, which did not appear in the specification filed, introduces new concepts and violate the description requirement of the first paragraph of 35 USC 112.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 5-9, 15-16, 18, 23, 25-27, 30-31 and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23-25 recite “substantially free of serum electrolytes”. The specification does not define the term and leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear. Since the term “substantially free” relates to a certain degree of concentration of serum electrolytes (“conventional additives” page 6, last paragraph) not present in said composition, one having ordinary skill in the art would have not understood what is the requisite degree of electrolytes to make the claimed composition “substantially free of serum electrolytes”. Claims 1-3, 15, 27, 30 and 35 are grouped together with this ground of rejection.

Claim 1 recites “orally administering the liquid drink composition to the patient in an amount and frequency sufficient to reduce patient plasma to a clinically-acceptable level or to maintain this level or both”. It appears in view of the instant specification (page 3, the first paragraph; page 4, lines 10-13) and the original claim 1, line 5 filed 12/31/03) that the desired effect of the instant invention such as the treatment of hepatic encephalopathy is achieved by reducing plasma levels of ammonia, not “plasma” itself. Apparently, this inconsistency between the specification and the claims leads to lack of clarity of the claims as a whole. Claims 1-3, 15, 27, 30 and 35 are grouped together with this ground of rejection.

For the examination purpose, the term “plasma” is interpreted as “ammonia plasma level”.

With respect “a clinically-acceptable level or to maintain this level” in claims 1 and 33, the specification discloses that the reduction of plasma levels of ammonia has been clinically observed to improve HE in many cases, and evaluation of ammonia blood levels of hyperammonia is widely routine in suspected cases (page 2, lines 1-3). Although the specification discusses the correlation between ammonia level and hepatic encephalopathy (page 3, lines 5-6; page 4, lines 10-12), there is no specific reference, in term of the range of ammonia concentration, in the specification that what concentration level is considered to be “clinically-acceptable level” of ammonia in plasma.

It appears in view of the instant specification that the applicant relies on the clinician’s routine knowledge in determining appropriate ammonia plasma level acceptable for the treatment of hepatic encephalopathy.

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Contrary to the applicant's reliance on the relative skill of the artisan in ascertaining "clinically-acceptable level" ammonia, the ammonia laboratory test is considered unreliable and is not in common clinical use to monitor the effectiveness of treatment of hepatic encephalopathy. Since hepatic encephalopathy can be caused by the build-up of variety of toxins in the blood and brain, it is generally recognized that blood ammonia levels correlate poorly with the degree of impairment ("Ammonia", www.labtestsonline.com, 2004; "Encephalopathy, Hepatic", www.emedicine.com, 2006").

As discussed above, the state of art is not certain about what is "a clinically-acceptable level" of plasma ammonia. Consequently, the applicant's recitation of term "a clinically-acceptable level, or to maintain this level or both" without the clear definition of the term in the specification leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Claims 1-3, 5-9, 15-16, 23, 26-27, 30-31 and 33-36 are grouped together with this ground of rejection.

Dependent claim 13 which further depends on the claim 12, recites that said dosage composition further comprises about 10 to 30gm of lactulose. It appears in view of claim 10, the claim 12 composition contains two (main) ingredients such as PEG and lactulose. The term "further comprises" is used to incorporate the additional ingredient into composition. Consequently, "further comprising about 10 to 30 gm of lactulose" makes the claim 13 vague and unclear and leaves the reader in doubt as to the meaning of the invention to which they refer,

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thereby rendering the definition of the subject-matter of said claims unclear. Claims 13, 18 and 25 are grouped together with this ground of rejection.

For the examination purpose, “further comprising” is interpreted as “comprising”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 15, 27, 30 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Cleveland et al. (US 6645481).

The instant claims are related to the treatment of a patient with or at risk of hepatic encephalopathy characterized by hyperammonemia, comprising administering a composition comprising polyethylene glycol, substantially free of serum electrolytes; formulating a liquid drink by admixing the composition with a pharmaceutically acceptable aqueous carrier; and orally administering the liquid drink composition to the patient in an amount and frequency sufficient to reduce patient plasma to a clinically-acceptable level, or to maintain this level, or both, without cleansing the bowel. Further limitations include “a dry composition consisting essentially of PEG” (claim 2); “single dosages each comprising from about 5 to 35 gm of dry PEG dissolved in aqueous liquid” (claim 3), “the PEG is solid at room temperature” (claim 15),

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“administered on a continuing basis in at least one single dosage per day” (claims 27 and 35); and “administered sufficient to alleviate constipation in the patient” (claim 30).

The interpretation of the instant claims (given “the reasonably broadest interpretation”) does not limit the patient population as to the patient having hepatic encephalopathy. Rather “at risk of” permits to include any patient population with or without the hepatic encephalopathy condition. In other words, the instantly claimed patient “at risk of” is not required to have hepatic encephalopathy.

Cleveland teaches a composition consisting essentially of polyethylene glycol, preferably dispersed and or dissolved in an aqueous medium (e.g., water or juice) or in pre-mixed liquid for, or in solid form for oral ingestion (e.g., as solid wafers, capsules or tablets) that is useful for the treatment of constipation, wherein said composition contains a dosage from about 5 to about 200 g of polyethylene glycol, preferably from about 10 to about 34g of polyethylene glycol per dose up to four times a day (abstract; column 2, lines 39-54; claims 1, 6-11) and wherein said composition is substantially free of electrolytes (abstract; claim 2). Cleveland also teaches that PEG in solid forms are conveniently dispersed/dissolved in from about 6 to about 10 fl. Oz (i.e., about 10-12 times the weight of the solid PEG) of water, and the mixture ingested orally as necessary for relief of symptoms (column 2, lines 45-50); PEG polymer used in the formulation is solid at room temperature (column 2, lines 28-31); and the administration of said composition provides satisfactory bowel movement on daily basis, after taking the composition for 1-4 days (column 3, line 66 thru column 4, line 1).

Although Cleveland is silent about “hepatic encephalopathy characterized by hyperammonemia” and whether the administration of said composition is to “reduce patient

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plasma to a clinically-acceptable level, or to maintain this level or both, without cleansing the bowel”, the referenced method of administering the same composition to the same patient group (e.g., patient with constipation as seen in the dependent claim 30), in overlapping dosage amounts, inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by applicant anticipates applicant’s claims even absent explicit recitation of the mechanism of action.

With respect to “a dry composition” in claim 2, the referenced solid composition (e.g., tablet or wafer) “metes and bounds” the claimed limitation. Thus, Cleveland anticipates the claimed invention.

With respect to “a continuing basis in at least one single dosage per day”, the referenced teaching in administering said composition in up to four times a day or daily for 1-4 days “metes and bounds” the claimed limitation. Thus, Cleveland anticipates the claimed invention.

8. Claims 10 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bond et al. (Journal of Laboratory and Clinical Medicine, 1975, 85(4), pp. 546-55).

The instant claims are drawn to a composition comprising PEG and lactulose. Further limitation includes “substantially free of serum electrolytes”.

Bond teaches mixture comprising 10 or 20 gm of lactulose and 2 to 3 gm of PEG.

Applicant’s statement of intended purpose, “for treatment of a patient with or at risk HE characterized by hyperammonemia” is not limited to the interpretation of the instant claims. Thus, Bond anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 10-14, 17-21, 24-25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleveland et al. (US 6645481) in view of “Duphalac Dry” Information Brochure (Solvay Pharmaceuticals, Publication date 27, May 1994).

The teaching of Cleveland has been discussed in above 35 USC 102(a) rejection.

“Duphalac Dry” Information Brochure teaches use of lactulose for the treatment of constipation and portal systemic encephalopathy, wherein lactulose is prepared in ready-to-mix powder form (10g/sachet). The brochure also teaches the dosage information (5 to 30gm per day for constipation; 20-35 gm three times per day for the portal systemic encephalopathy).

The teaching of Cleveland differs from the claimed invention in (i) the combination of PEG and lactulose in a composition or single dosage composition and (ii) the specific dosage amounts of each ingredient, namely “about 0.15 to 3.5 parts by weight PEG to 1 part by weight lactulose” (claim 11), “5 to 35 gm of PEG” (claim 12), “about 10 to 30 gm of lactulose” (claim 13), “about 10 to 20 gm PEG and 10 to 20 gm lactulose” (claim 14) and “about 0.5 to 3 parts by

weight PEG to 1 part by weight lactulose”. To incorporate such teaching into the teaching of Cleveland, would have been obvious in view of “Duphalac Dry” Product Information Brochure that teaches use of lactulose for the treatment of constipation.

Above references in combination make clear that PEG and lactulose have been individually used for the treatment of constipation. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

With respect to the determination of the specific dosage amounts of each active ingredient, those of ordinary skill in the art would have been readily determined effective dosage amounts as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed in Cleveland and the product information brochure. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Applicant’s statement of intended purpose, “for treatment of a patient with or at risk HE characterized by hyperammonemia” is not limited to the interpretation of the instant claims. Thus, the references in combination makes obvious the instant invention.

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10. Claims 5-9, 16, 23, 26, 31, 33-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleveland et al. (US 6645481) in view of "Duphalac Dry" Information Brochure (Solvay Pharmaceuticals, Publication date 27, May 1994), and further in view of Roblin et al. (Gastroenterol Clin Biol 1994, 18(12): 1146).

The claims read on a method for the treatment of a patient with or at risk of HE characterized by hyperammonemia, comprising administering to the patient a composition comprising PEG and lactulose in an amount and frequency sufficient to reduce patient plasma ammonia to a clinically-acceptable level, or to maintain this level or both. Further limitations include "the composition is formulated as a liquid drink by admixture with a pharmaceutically-acceptable aqueous carrier and orally administered to the patient" (claim 34), "the composition is administered on a continuing basis in at least one single dosage per day" (claim 36), "the amount of the composition administered is sufficient to alleviate constipation in the patient" (claim 31), "wherein the composition is administered on a continuing basis in at least one single dosage per day" (claim 26); "substantially free of serum electrolytes" (claim 23), "the PEG is solid at room temperature" (claim 16), "about 0.15 to 3.5 parts by weight PEG to 1 part by weight lactulose" (claim 5), "about 0.5 to 3 parts by weight PEG to 1 part by weight lactulose" (claim 6), "about 5 to 35 gm of dry PEG dissolved in the aqueous carrier" (claim 7), "about 10 to 30 gm of dry lactulose dissolved in the aqueous carrier" (claim 8) and "about 10 to 20 gm PEG and 10 to 20 gm lactulose" (claim 9).

The teaching of Cleveland has been discussed above 35 USC 102(a) rejection.

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The teaching of “Duphalac Dry” Information Brochure has been discussed above 35 USC 103(a) rejection.

Roblin is being supplied as a supplemental reference to demonstrate the art recognition in using polyethylene glycol for the treatment of hepatic encephalopathy.

The teaching of Cleveland differs from the claimed invention in (i) the use of composition comprising combination of PEG and lactulose and (ii) the specific dosage amounts of each ingredient, “about 0.15 to 3.5 parts by weight PEG to 1 part by weight lactulose” (claim 5), “about 0.5 to 3 parts by weight PEG to 1 part by weight lactulose” (claim 6), “about 5 to 35 gm of dry PEG dissolved in the aqueous carrier” (claim 7), “about 10 to 30 gm of dry lactulose dissolved in the aqueous carrier” (claim 8) and “about 10 to 20 gm PEG and 10 to 20 gm lactulose” (claim 9).

To incorporate such teaching into the teaching of Cleveland, would have been obvious in view of “Duphalac Dry” Product Information Brochure that teaches use of lactulose for the treatment of constipation.

As discussed above (35 USC 102(a) rejection), the interpretation of the instant claims (given “the reasonably broadest interpretation”) does not limit the patient population as to the patient having hepatic encephalopathy. Rather “at risk of” permits to include any patient population with or without the hepatic encephalopathy condition. In other words, the instantly claimed patient “at risk of” is not required to have hepatic encephalopathy.

Thus, it is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been

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individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

With respect to the determination of the specific dosage amounts of each active ingredient, those of ordinary skill in the art would have been readily determined effective dosage amounts as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed in Cleveland and the product information brochure. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Alternatively, as evidenced by the instant claim 31 (“wherein the amount of the composition administered is sufficient to alleviate constipation in the patient), said composition in amounts sufficient to alleviate constipation would provide a therapeutic effect for the same ultimate purpose as disclosed by the applicant. Thus, the references in combination (Cleveland and “Duphalac Dry” Product information Brochure) make obvious the instant invention.

Even if the examiner gives different interpretation of the term “a patient with or at risk of HE characterized by hyperammonemia”, one having ordinary skill in the art would have

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expected as taught by Roblin that the combination of polyethylene glycol and lactulose taught by (Cleveland and the product information brochure) would provide therapeutic utility in the treatment of HE.

Above references in combination make clear that PEG and lactulose have been individually used for the treatment of constipation as well as hepatic encephlopathy. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

One having ordinary skill in the art would have been motivated to combine the references and make such modification such that the pharmacological activity of combination would be greatly enhanced while the adverse effects associated with the drugs would be decreased. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

11. No Claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to read 'B. Kwon', with a long horizontal line extending to the right.